

Dec 22, 2022

EU Declaration of Conformity

We the manufacturer, Guangdong Transtek Medical Electronics Co., Ltd. (manufacturing location: Zone A, No. 105 Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China), hereby declare under our sole responsibility that the equipment below complies with the 2014/53/EU Radio Equipment Directive.

Product	Blood Pressure Monitor
Model	BT106
Software	A01
Accessories	Cuffs BT195, BT196

The following standards were applied for the evaluation of the compliance with this directive:

Safety	IEC 60601-1:2005+AMD1:2012
Article3.1(a)	IEC 60601-1-11:2015
EMC	EN 301 489-1 V2.2.3
Article3.1(b)	Draft EN 301 489-52 V1.1.2
Radio	EN 301 908-1 V13.1.1
Article3.2	EN 301 908-13 V13.1.1
Health	EN IEC 62311:2020
Article3.1(a)	

Ken Zhai

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Product manager